K041233

JUL 2 8 2004

HydroCision
100 Burtt Rd. Suite G01
Andover, MA 01810
Tel: 978-474-9300
Fax: 978-474- 5037

510K Summary of Safety and Effectiveness
May 5, 2004
Modification to the
HydroCision, Inc. ArthroJet System with Cautery

1. Sponsor Name

HydroCision, Inc
100 Burtt Rd. Suite G01
Andover, MA 01810
Tel: 978-474-9300
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name:	ArthroJet Resector XT
Common/Usual Name:	Arthroscope and Accessories Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Arthroscope and Accessories Electrosurgical Cutting and Coagulation Device and Accessories

3. Identification of Legally Marketed Device

HydroCision ArthroJet with Cautery, TurboBurr and Curette, K032529

4. Device Description

The HydroCision ArthroJet System with Cautery, TurboBurr and Curette employs two basic system components to achieve its mechanism of action:

- the reusable power console unit
- the sterile, disposable pump cartridge, handpiece and tubing assembly

The handpiece component of the sterile, disposable assembly is comprised of two principal components:

- a high pressure fluid conduit with integral fluidjet nozzle
- a low pressure collection tube.

The high pressure conduit consists of a hollow stainless steel tube with a nozzle at the distal end. The collection tube incorporates an opening at its distal end such that the fluidjet is directed into the opening when in use. Because of the hydrodynamic design of the fluidjet/collection tube combination, the orifice serves to pull excised tissue fragments and other debris into the collection tube. Controls on the front panel allows the user to adjust the pressure, from zero to a factory pre-set limit of 15,000 psi.

5. Intended Use

The HydroCision ArthroJet System with Cautery, TurboBurr, and Curette is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting, ablation and shaping of soft tissue, and drilling, reaming, decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and minimally invasive spinal surgeries and small and large joint arthroscopic procedures.

This is the same intended use as the currently marketed HydroCision ArthroJet System with Cautery, TurboBurr, and Curette.

6. Comparison of Technological Characteristics

Substantial equivalence of the HydroCision ArthroJet System with Cautery, TurboBurr and Curette is based on:

1. Design similarities between the proposed System and the currently marketed HydroCision ArthroJet with Cautery, TurboBurr and Curette
2. Performance testing. The proposed and currently marketed HydroCision ArthroJet with Cautery, TurboBurr and Curette are very similar in terms of size, materials of construction, performance characteristics, and basic design. The differences have no effects on the performance or safety of the HydroCision ArthroJet System with Cautery, TurboBurr and Curette.

7. Performance Testing

Bench testing was conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2004

HydroCision, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K041233
Trade/Device Name: HydroCision ArthroJet System with Cautery, TurboBurr, and Curette
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: June 25, 2004
Received: June 29, 2004

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041233

Device Name: HydroCision ArthroJet System with Cautery, TurboBurr, and Curette

Indications For Use:

The HydroCision ArthroJet System with Cautery, TurboBurr, and Curette is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting, ablation and shaping of soft tissue, and drilling, reaming, decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and minimally invasive spinal surgeries and small and large joint arthroscopic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041233